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# PUBLIC SUBMISSION

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**Docket:** NRC-2016-0190

Program-Specific Guidance About Commercial Radiopharmacy Licenses

**Comment On:** NRC-2016-0190-0002

Program-Specific Guidance About Commercial Radiopharmacy Licenses; Draft NUREG for Comment

**Document:** NRC-2016-0190-DRAFT-0002

Comment on FR Doc # 2017-01546

## Submitter Information

**Name:** David Reindl

## General Comment

See attached file(s)

## Attachments

STC-17-012 Wisconsin Comments

RECEIVED

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RULES OF PROCEDURE

SUNSI Review Complete  
Template = ADM - 013  
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Add= S. Daibes (SFD)



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March 24, 2016

Cindy Bladey  
Office of Administration  
Mail Stop: OWFN-12-H08  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

RE: Docket ID NRC-2016-0190 OPPORTUNITY TO COMMENT ON DRAFT NUREG-1556, VOLUME 13, REVISION 2, "CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES: PROGRAM-SPECIFIC GUIDANCE ABOUT COMMERCIAL RADIOPHARMACY LICENSES" (STC-17-012)

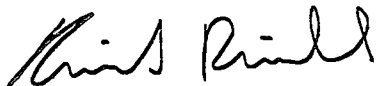
Dear Ms. Bladey,

The State of Wisconsin, Radioactive Materials Program has reviewed the above document and submits the following comments:

1. Page 8-11, Line 5: Delete "virtually all".
2. Page 8-43: Lines 1-3 should be printed directly after page 8-42 lines 36-38 and not be separated by Table 8-3.
3. The Part 37 information is very distracting and should be collected in the back of the document as an appendix. Part 37 applies to very few radiopharmacies.
4. Page J-4: The maximum permissible contamination limits are not correct. In 2014, DOT raised the contamination limits to 240 dpm/cm<sup>2</sup> for beta/gamma/low-toxicity alphas and 24 dpm/cm<sup>2</sup> for other alpha-emitters.
5. Page L-1: The suggested frequency for dose calibrator linearity testing (quarterly) does not match the suggested frequency given in the Medical NUREG (annually). These NUREGs should give the same frequency for linearity testing.
6. Page N-1: Consider either expanding the item in lines 10-13 or making it more generic to incorporate other generator systems (e.g., Ga-Ge).
7. Appendix N: Add guidance for compounding alpha-emitting radioisotopes. This should address contamination control, in particular.

8. Page N-5, lines 23-25: DHS supports restricting the minor spill designation to no more than five times the lowest ALI for each radionuclide.
9. Page N-5, line 42: Delete "the requirements in".
10. Page O-2 states "All areas where radioactive materials are eluted, prepared, assayed, dispensed, or packaged for transport should be surveyed daily." The guidance should specify whether daily surveys are limited to ambient radiation level surveys or whether they should also include contamination surveys.
11. Page O-3 states "Licensees should establish action levels for the detection of contamination. Typically, licensees establish action levels that are twice the known background radiation level." DHS disagrees with the removal of table R.1 concerning recommended action levels. DHS suggests developing a recommended action level table that is based on the ALI, for example a high-medium-low designation based on whether the lowest ALI is in nanocuries, microcuries or millicuries.
12. We have struggled recently with existing radiopharmacy guidance for alpha surveys, including developing appropriate action levels based on ALARA considerations and the limitations of well counting equipment. Appendix O should provide more guidance specific to alpha surveying. For example, do the action levels apply to each isotope in a decay chain separately or to the decay chain in total? What types of surveys should be performed in areas where alpha radiopharmaceuticals are compounded and how often? This NUREG should emphasize efficiency determination for performing contamination surveys for daughter isotopes in equilibrium with a parent nuclide.

Sincerely,



David Reindl  
Nuclear Engineer  
Radioactive Materials Program  
State of Wisconsin